

Statement of the problem

4.

Evidence of Tom Thumb design inputs containing the outputs of risk management could not be provided at this assessment (ref Tom Thumb specification document # 2247 dated 6 June 1997 and Tom Thumb risk management file dated 29/9/2017)

4.

Root Cause Analysis

We have never had the original Tom Thumb design inputs, as the original unit was designed and developed by a RVI Royal Victoria Infirmary Newcastle in 1992-1993 and the design modified in 1993 to its current design, when clinical trials were carried out by the hospital.

The Tom Thumb outputs of risk management, from 1998, were not on the digital system at the time of the audit. We have a paper risk assessment from 1998 that we did in house for the Tom Thumb Technical files. But the original files from RVI are no longer available.

4.

Immediate Action

It has not been possible, up until now, to provide the original design inputs as we had not found them.

We have now located, in the paper files in archiving, a design brief from RVI in 1993 that offers the original design inputs. It states "Prototype supplied by RVI". Early design drawings can be provided.

These will now be uploaded to the Digital System.

We will upload the Risk Analysis report from 1998.

4.

Corrective Action

The missing documentation will be added to the system as well as other relevant documentation, relating to the Tom Thumb.

We can ensure relevant historic documents are brought in to the new system when we find them.

We will make it easily locatable in the Digital System.

This information is so old no one remembers that we have it, so it is impossible to produce it without investigation as to its existence and location.

Design files of Tom Thumb: circa 1997 or before, were collated retrospectively into our Digital Technical files. Original designers are now retired or deceased and original

files no longer available.
please refer to the MDD and NB-MED/2.5.1/Rec5 Page 2.